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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|--------------------------------|------------------|
| 10/790,661 | 03/01/2004 | Fred H. Burbank | R0367-00104 | 9566 |
| 7590 Edward J. Lynch DUANE MORRIS LLP Spear Tower, Suite 2000 One Market San Francisco, CA 94105 | | 03/23/2007 | EXAMINER SZMAL, BRIAN SCOTT | |
| | | | ART UNIT 3736 | PAPER NUMBER |
| SHORTENED STATUTORY PERIOD OF RESPONSE | | MAIL DATE | DELIVERY MODE | |
| 3 MONTHS | | 03/23/2007 | PAPER | |

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

| | | |
|------------------------------|-------------------------|------------------|
| Office Action Summary | Application No. | Applicant(s) |
| | 10/790,661 | BURBANK ET AL. |
| | Examiner Brian Szmal | Art Unit 3736 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on _____.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1 and 40-62 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1 and 40-62 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 01 March 2004 is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date: _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date <u>See Continuation Sheet</u> . | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| | 6) <input type="checkbox"/> Other: _____ |

Continuation of Attachment(s) 3). Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date
3/1/04;5/24/05;11/15/05;6/23/06; 7/11/06;8/23/06;10/5/06.

Claim Objections

1. Claims 45-48 and 50-52 are objected to because of the following informalities: The claims cite "the electrosurgical proximal tissue cutting element". There is a lack of antecedent basis within the claims for "the electrosurgical proximal tissue cutting element". Appropriate correction is required.
2. Claim 41 is objected to because of the following informalities: The claim cites "the radial extended arcuate position". There is a lack of antecedent basis in the claims for "the radial extended arcuate position". Appropriate correction is required.
3. Claim 42 is objected to because of the following informalities: In line 2, "move" should be spelled as "moves" in order to be grammatically correct. Appropriate correction is required.
4. Claims 50 and 52 are objected to because of the following informalities: Both claims disclose the use of "it". The use of "it" renders the claims indefinite due to the fact that "it" is not clearly defined within the claims. Appropriate correction is required.
5. Claim 59 is objected to because of the following informalities: In line 6, "from and to" appears as though it should read as "from a" in order to be grammatically correct. Appropriate correction is required.

Specification

6. The abstract of the disclosure is objected to because the abstract exceeds 150 words. Correction is required. See MPEP § 608.01(b).

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

8. Claims 1, 40-43 and 47-62 are rejected under 35 U.S.C. 102(e) as being anticipated by Patterson et al (5,941,869).

Patterson et al disclose a means for controlled removal of tissue and further disclose a distal end adapted for entry into a patient's body; an electrosurgical cutting element disposed on a distal portion of the instrument, which is actuatable between a radially retracted position and a radially extended position, relative to the axis, which is movable in the radially extended position to isolate a desired tissue specimen from surrounding tissue by defining a peripheral margin about the tissue specimen and which is insulated from body tissue in the retracted position; an elongate shaft that has a longitudinal axis and a distal end; an electrical conductor configured to electrically interconnect the electrosurgical cutting element to a high frequency electrical power source; the electrosurgical cutting element has a proximal end and a distal end and which is configured to move one end closer to the other end to effect radial extension from the retracted position to the radial extended arcuate position; the distal end of the

electrosurgical cutting element is fixed and the proximal end moves toward the distal end; the cutting element is rotatable about the longitudinal axis while in the extended position; a sheath which is axially movable between distal and proximal positions for selectively covering and uncovering the cutting element; a proximal driver unit for controlling radial expansion and retraction of the cutting element and rotation of the cutting element about the longitudinal axis; the proximal driver unit further controls the axial movement of the shaft and axial movement of the sheath; the cutting element is capable of segmenting the tissue specimen after it has been isolated from the surrounding tissue; the cutting element is actuatable to a plurality of additional radially extended positions and rotatable about the longitudinal axis in the plurality of extended positions; a cannula having a lumen for providing a passageway into the patient's body; the distal portion of the shaft is provided with a recess configured to receive the cutting element; the recess is provided at least in part with a lining of insulating material to insulate the cutting element; inserting the probe into tissue; insulating the active cutting element from the tissue; energizing the active element; and exposing the energized element. See Figures 11, 12 and 37-39; Column 12, lines 64-67; Column 13, lines 1-15 and 46-60; Column 16, lines 29-51; Column 18, lines 64-67; Column 19, lines 1-7; and Column 27, lines 4-49.

9. Claims 1, 40-43, 47, 50, 51, 54, 61 and 62 are rejected under 35 U.S.C. 102(e) as being anticipated by McGuckin, Jr. (6,280,450 B1).

McGuckin, Jr. discloses a means for removing tissue from a breast and further discloses a distal end adapted for entry into a body; an electrosurgical cutting element

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on a distal portion of the instrument that is actuatable between a retracted and an extended position and movable in the extended position to isolate a tissue specimen from surrounding tissue and is insulated from body tissue in the retracted position; an electrical conductor configured to electrically interconnect the cutting element to a high frequency power source; the cutting element is configured to move one end closer to the other end to effect extension from the retracted position to the extended position; the distal end is fixed and the proximal end moves toward the distal end; the cutting element is rotatable when in the extended position to isolate the specimen; a sheath axially movable between distal and proximal positions for selectively covering and uncovering the cutting element; the cutting element is configured to segment the specimen after it has been removed from the surrounding tissue; the cutting element is configured to segment the specimen; removing the specimen from the body through a cannula; and a source of radiofrequency energy. See Figures 1, 4 and 5; Column 5, lines 56-67; Column 6; and Column 7, lines 1-47, in particular lines 31-44.

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

11. Claims 44-46 are rejected under 35 U.S.C. 103(a) as being unpatentable over Patterson et al (5,941,869) as applied to claim 40 above, and further in view of Eggers et al (6,106,524).

Patterson et al, as discussed above, disclose an electrosurgical means of removing tissue, but fail to disclose the use of a monopolar electrode or a bipolar electrode.

Eggers et al discloses an electrosurgical device and further disclose the use of a monopolar electrode or a bipolar electrode. See Column 2, lines 19-35.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to include the use of either a monopolar electrode or a bipolar electrode, since it is well known in the art to use either type of electrode in electrosurgery.

12. Claims 44-46 are rejected under 35 U.S.C. 103(a) as being unpatentable over McGuckin, Jr. (6,280,450 B1) as applied to claim 40 above, and further in view of Eggers et al (6,106,524).

McGuckin, Jr., as discussed above, discloses a means of removing tissue from a breast using electrosurgical elements, but fail to disclose the use of a monopolar electrode or a bipolar electrode.

Eggers et al discloses an electrosurgical device and further disclose the use of a monopolar electrode or a bipolar electrode. See Column 2, lines 19-35.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to include the use of either a monopolar electrode or a bipolar

electrode, since it is well known in the art to use either type of electrode for removing tissue from the body.

13. Claims 52 and 53 are rejected under 35 U.S.C. 103(a) as being unpatentable over McGuckin, Jr. (6,280,450 B1).

McGuckin, Jr., as discussed above, disclose a means for removing tissue from the body through the use of electrosurgical cutting elements when the elements are expanded and rotated about an axis. It would have been obvious to one of ordinary skill in the art at the time the invention was made, to utilize the tissue removal device of McGuckin, Jr. to segment tissue as the cutting elements are being retracted, and peripherally segment the specimen by actuating the cutting element at a plurality of extended positions and rotating the cutting element, since a surgeon would be able to operate the device in multiple different ways to obtain the specimen.

14. Claims 48 and 49 are rejected under 35 U.S.C. 103(a) as being unpatentable over McGuckin, Jr. (6,280,450 B1) as applied to claim 40 above, and further in view of Patterson et al (5,941,869).

McGuckin, Jr., as discussed above, discloses a driver unit for rotating the cutting elements about the longitudinal axis, but fails to disclose a driver unit for controlling the expansion and retraction of the cutting element; and the driver unit further controls axial movement of the shaft and axial movement of the sheath.

Patterson et al, as discussed above, disclose a means for removing tissue form the body, and further disclose a driver unit for controlling the expansion and retraction of

the cutting element; and the driver unit further controls axial movement of the shaft and axial movement of the sheath. See Column 13, lines 46-60.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the means of McGuckin, Jr. to include the use of a driver unit to control the expansion and retraction of the cutting element, as per the teachings of Patterson et al, since it would provide a controlled means of operating the cutting element while preventing damage to surrounding tissue.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Szmal whose telephone number is (571) 272-4733. The examiner can normally be reached on Monday-Friday, with second Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571) 272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



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